

SN 09/995,304
Docket No. S-94,769
In Response to Office Action dated October 6, 2004

REMARKS

Applicants appreciate the courtesy shown by the Office, as shown by the Office Action mailed on October 6, 2004, and the March 28, 2004, telephone interview between Applicants' attorney and Examiner Pensee Do. In that Office Action, the Examiner rejected Claims 1-6, 8-13, and 16, and objected to Claims 7, 14, and 15. As such, Claims 1-63 remain in the case with none of the claims being allowed.

The October 6 Office Action and March 28 interview have been carefully considered. After such consideration, Claims 1-4 and 12-15 have been amended. Applicants respectfully request reconsideration of the application in light of the accompanying amendment and remarks presented herein.

In the March 28 interview, Applicants' attorney pointed out to the Examiner that the Claims listed in the Response to Election/Restriction Requirement (referred to hereinafter as "the Election"), mailed on September 10, 2004, included a listing of claims that differed from the claims submitted in the original application, filed on November 27, 2001 (also referred to hereinafter as "original claims"). It was decided in the March 28 interview that the claims submitted in the Election of September 10 would be disregarded. The amendments to the claims and remarks contained herein are therefore directed to the claims as originally filed on November 27, 2001, and the listing of claims herein replaces all prior versions, and listings, of claims in the application.

Rejections under 35 U.S.C. §112

Claims 1-16 are rejected under 35 U.S.C. §112, second paragraph, as being indefinite.

The Examiner states that Claim 1 is confusing for reciting "re-sorting" and "sorting said distinct populations of magnetic microspheres by passage through a magnetic separator." The Examiner further states that it is unclear as to how the magnetic separator distinguishes different populations of microspheres.

Regarding the Examiner's assertion that Claim 1 is confusing for reciting "re-sorting," Applicants submit that Claim 1 as filed on November 27, 2001 did not recite

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"re-sorting." Applicants further submit that Claim 2 has been amended to replace "re-sorting" with --sorting--.

Regarding the phrase "sorting said distinct populations of magnetic microspheres by passage through a magnetic separator," Claim 1 has been amended to recite the limitation that the different populations of microspheres are separated according to magnetic moment. Accordingly, Applicants submit that the claim now clearly describes how the separator distinguishes the different populations of microspheres, and the rejection of Claim 1 under 35 U.S.C. §112, second paragraph, is therefore overcome.

The Examiner states that an unnumbered claim is confusing for reciting "prior to an initial sorting stage," and asks when the "initial sorting stage" occurred. Applicants submit that original Claim 4 includes this term. Claim 4 has accordingly been amended to recite the limitation that the magnetic microspheres are passed through a magnetic field *prior to* sorting. Applicants therefore submit that the claim now clearly states that magnetization of the microspheres takes place prior to sorting, and that the rejection of Claim 4 under 35 U.S.C. §112, second paragraph, is overcome.

The Examiner states that, in Claims 11-14, the term "said forming magnetic microsphere" lacks antecedent support. Applicants submit that, in the original Claims 12-15 recite the term "said forming magnetic microsphere." Accordingly, Claim 1 has been amended in part to introduce the limitation that each of the microspheres includes a plurality of magnetic particles. Applicants submit that the amendment provides proper antecedent support for Claims 12-15 and the rejection of the claims under 35 U.S.C. §112, second paragraph, is therefore overcome.

The Examiner also states that Claim 14 is indefinite, because the recitation of "adapted for" in the last two lines of the claim is unclear. The Examiner further states that the role of the second reactive functionality bound to the non-magnetic particle is indefinite. Applicants submit that, in the original claims, filed on November 27, 2001, Claim 15 recites the recitations of "adapted for" and the first and second functionalities. Accordingly, Claim 15 has been amended to recite the limitation that the second functionality reacts with the first functionality to form the magnetic microsphere. The second reactive functionality is bound to a non-magnetic microsphere, and the first reactive functionality is bound to a magnetic particle, and the second and first reactive

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functionalities react to form magnetic microspheres. See page 10, lines 16-20, of the specification. Receptors may bind to either microspheres or the magnetic particles. See, for example, page 11, lines 1-3, of the specification. Applicants submit that, because amended Claim 15 now clarifies the role of the second functionality, the rejection of Claim 15 under 35 U.S.C. §112, second paragraph, is therefore overcome.

Rejections under 35 U.S.C. §102

Claims 1, 2, 5, 6, 10, and 16 are rejected under 35 U.S.C. §102(b) as being anticipated by Wilson (U.S. Patent 5,392,097).

Applicants submit that independent Claim 1 has been amended to recite the limitation that each of the magnetic microspheres includes a plurality of magnetic particles, wherein the magnetic particles are either coated, imbedded in the magnetic microspheres, or immobilized on a surface of or within the magnetic microspheres.

Applicants submit that, in order to anticipate under §102, a reference must teach every element of the claimed invention. Accordingly, Applicants submit that Wilson does not teach all the limitations of amended Claim 1 described above, but instead teaches layered structures separated by antimagnetic material. See column 3, lines 8-9 and 61-4; column 5, lines 47-50; and column 8, lines 28-51 of the reference.

Because the reference does not teach all of the limitations of amended independent Claim 1, the rejection of the claim and those claims dependent thereon under 35 U.S.C. §102(b) as being anticipated by Wilson is therefore successfully overcome.

Claims 1-6, 8-13, and 16 are rejected under 35 U.S.C. §102(b) as being anticipated by Miltenyi (U.S. Patent 5,543,289).

Applicants submit that Miltenyi does not teach all the limitations of amended Claim 1. As presented above, Claim 1 has been amended to include the limitation that the magnetic microspheres each include a plurality of magnetic particles that are either coated, imbedded in the magnetic microspheres, or immobilized on a surface of or within the magnetic microspheres. Miltenyi does not teach microspheres comprising a plurality of magnetic particles.

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Applicants therefore submit that, because the reference does not teach all of the limitation of amended Claim 1, the rejection of the claim and those claims dependent thereon under 35 U.S.C. §102(b) as being anticipated by Miltenyi is therefore successfully overcome.

Claims 1, 3, 4, 6, 10, 12, 13, and 16 are rejected under 35 U.S.C. §102(e) as being anticipated by Blankenstein (U.S. Patent 6,432,630).

Applicants submit that Blankenstein does not teach all of the limitations of amended Claim 1.

Applicants submit that Blankenstein does not teach the separation of two distinct populations of magnetic microspheres, wherein each population has a specific magnetic moment, according to their respective magnetic moments. The reference instead teaches the separation of magnetically labeled cells or particles from *non-magnetic* particles. See column 12, lines 53-56 of the reference.

As previously presented, Claim 1 has been amended to include the limitation that the magnetic microspheres each include a plurality of magnetic particles that are coated, imbedded in the magnetic microspheres, or immobilized on a surface of or within the magnetic microspheres. The reference does not teach microspheres having these structures, but instead describes cells or particles coupled to magnetic microbeads (column 6, lines 46-47; and column 12, lines 53-55).

The Examiner states that, since the flow channel of Blankenstein is formed from organic polymer material or glass, "...it is equivalent to the magnetic beads [flowing through the flow channel], are being [sic] *embedded* within a material that is made up of organic polymer material or glass (emphasis added)." Applicants respectfully disagree with the Examiner's position. Applicants submit that "embed" (or "imbed") is commonly understood to mean "to fix firmly in a surrounding mass" or "to make an integral part of." Applicants submit that the magnetic beads are neither "fixed firmly" in the flow channel nor "made an integral part" of that channel. Thus, Blankenstein does not teach magnetic particles or microspheres that are embedded within a polymer or glass.

Because Blankenstein fails to teach all of the limitations of amended Claim 1, the rejection of the claim and the claims dependent thereon under 35 U.S.C. §102(e) as being anticipated by Blankenstein is successfully overcome.

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Rejection under 35 U.S.C. §103

Claims 3 is rejected under 35 U.S.C. 103(a) as being unpatentable over Wilson.

Applicants submit that, in order to establish a *prima facie* case of obviousness, a reference must either teach or suggest all of the limitations of the claimed invention. Applicants submit that, as previously presented herein, Wilson does not teach all of the limitations of amended Claim 1 and that Claim 3 depends from Claim 1 and therefore incorporates all of the limitations of the base claim by reference. Therefore, the rejection of Claim 3 under 35 U.S.C. 103(a) as being unpatentable over Wilson is successfully overcome.

In light of the amendments and remarks presented herein, Applicants submit that the case is in condition for immediate allowance and respectfully requests such action. If, however, any outstanding issues remain unresolved, the Examiner is invited to telephone the Applicants' counsel at the number provided below.

Respectfully submitted,

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